K102771

SOMATEX®
MEDICAL TECHNOLOGIES GMBH
MADE IN GERMANY
Rheinstraße 7d | D-14513 Teltow
Tel +49 (0) 3328 30 76-0 | Fax +49 (0) 3328 30 76-99
info@somatex.com | www.somatex.com

JUN 24 2011

510(k) SUMMARY

Biopsy Handy / MRI Biopsy Handy

Submitter:
Somatex Medical Technologies GmbH
Rheinstrasse 7d
14513 Teltow
Germany
Phone: +49 3328 3076 13
Fax: +49 3328 3076 99

Official Correspondent:
Susanne Raab

Regulatory Affairs Consultant
1480 Cambridge Street
Cambridge, MA 02139
Phone: 617 547 0628
Fax: 617 520 2136
e-mail: sbraab@comcast.net

Trade Name: Biopsy Handy / MRI Biopsy Handy

Common Name: Semiautomatic Biopsy System

Classification Name: Biopsy Instrument, 21 C.F.R. 876.1075

Regulatory Class: II

Product Code: KNW

Device Description: The Biopsy Handy and the MRI Biopsy Handy are sterile, single use, semiautomatic percutaneous soft tissue biopsy systems each consisting of the following major components: a device handle, a cannula, a stylet button, a stylet with a specimen chamber, a hub of the cannula, a guide bush, a slide and a pressure spring. In addition, the cannulas of the

SOMATEX®
MEDICAL TECHNOLOGIES GMBH
MADE IN GERMANY
Rheinstraße 7d | D-14513 Teltow
Tel +49 (0) 3328 30 76-0 | Fax +49 (0) 3328 30 76-99
info@somatex.com | www.somatex.com

proposed devices will be delivered with a protective tube.

Intended Use:

The Biopsy Handy and MRI Biopsy Handy are intended to obtain diagnostic samples of soft tissues for histological examination during a percutaneaous biopsy procedure. Both devices are indicated to be used with ultrasound or CT-Guidance techniques. Only the MRI Biopsy Handy is indicated to be used with magnetic resonance imaging (MRI) techniques.

Substantial Equivalence:

The Biopsy Handy and MRI Biopsy Handy are substantially equivalent to the Speedybell manufactured by Biopsybell S.A.S., which has been cleared by FDA on August 17, 2001 (K010735), and the Daum Biopsygun manufactured by Daum Corp., which has been cleared by FDA on March 6, 1998 (K974576). Specifically, the proposed devices and the predicate devices are all intended to obtain diagnostic samples of soft tissues for histological examination during a percutaneaous biopsy procedure. In addition, the proposed devices and the predicate device Speedybell are indicated to be used with ultrasound or CT-Guidance techniques. Finally, both the MRI Biopsy Handy and the predicate device Daum Biopsygun are indicated to be used with magnetic resonance imaging (MRI) techniques.

Furthermore, the Biopsy Handy and MRI Biopsy Handy are identical or similar in technology, design and material to the

SOMATEX®
MEDICAL TECHNOLOGIES GMBH
MADE IN GERMANY
Rheinstraße 7d | D-14513 Teltow
Tel +49 (0) 3328 30 76-0 | Fax +49 (0) 3328 30 76-99
info@somatex.com | www.somatex.com

predicate devices. Both the proposed and the predicate devices consist of the same primary components and the component materials of the proposed device and the predicate devices are substantially equivalent.

Based on the same intended use and the similiarities in technolgy, design and materials, the Biopsy Handy and MRI Biopsy Handy are substantially equivalent to their predicate devices. The minor technological differences between the proposed devices and the predicate devices do not raise new questions of safety and effectiveness.

Finally, biocompatibility, sterility, packaging and MR-testing demonstrate the safety and effectiveness of the proposed devices.

Date Prepared: February 24, 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Somatex Medical Technologies GmbH
% Ms. Susanne Raab
Regulatory Affairs Consultant
1480 Cambridge Street
Cambridge, Massachusetts 02139

JUN 24 2011

Re: K102771
Trade/Device Name: Biopsy Handy/MRD Biopsy Handy
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: June 23, 2011
Received: June 24, 2011

Dear Ms. Raab:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K102771

Device Name: Biopsy Handy / MRI Biopsy Handy

Indications for Use:

The **Biopsy Handy** and **MRI Biopsy Handy** are intended to obtain diagnostic samples of soft tissues for histological examination during a percutaneaous biopsy procedure. Both devices are indicated to be used with ultrasound or CT-Guidance techniques. Only the **MRI Biopsy Handy** is indicated to be used with magnetic resonance imaging (MRI) techniques.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark RP Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102771